

Docket No.: 085742-0010

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:  
Benjamin OSHLACK

Patent Number: 7,514,100

Application No.: 10/660,349

Filed: September 11, 2003

For: CONTROLLED RELEASE HYDROCODONE FORMULATIONS

**REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT**

**UNDER 37 CFR 1.705**

Mail Stop Patent Ext.  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is a request for reconsideration and recalculation of the patent term adjustment (PTA) under 37 CFR 1.705 for U.S. Patent No. 7,514,100, filed as Application No. 10/660,349 on September 11, 2003 and issued on April 7, 2009. This Request is accompanied by the \$200 fee required under 37 CFR 1.18(e).

37 CFR 1.705(d) requires that if the patent indicates or should have indicated a revised patent term adjustment, any request for reconsideration of the patent term adjustment indicated in the patent must be filed within two months of the date the patent issued and must comply with the requirements of paragraphs (b)(1) and (b)(2) of this section. Applicant believes that this request is timely because the two month deadline does not apply here. As stated below, the PTO miscalculated the PTA in the instant patent as a result of a misinterpretation of the "overlap" provision in 35 U.S.C. § 154.

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The PTO did not recognize its misinterpretation until the 2010 Federal Circuit decision in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010). Thus, the PTO could not have, at the time the instant patent issued, indicated a revised PTA. The failure of the PTO to have indicated (or should have indicated) a revised PTA triggers the two-month deadline. There was no such trigger in this case.

The facts specifying the correct PTA and the bases under 1.702 for the adjustment are set forth below. The instant patent is not subject to a terminal disclaimer.

### **Summary of Patent Term Adjustment under 35 U.S.C. § 154**

35 U.S.C. § 154 guarantees that the PTO will provide at least one notification under section 132 or a notice of allowance not later than 14 months after the date on which the application was filed, and subsequent notifications within four months of an applicant's response. PTO delays beyond these times are referred to as "A" delays.

35 U.S.C. § 154 further guarantees a no more than 3-year application pendency. This does not include time consumed by continued examination requested by the applicant. PTO delays beyond this 3-year period are referred to as "B" delays. PTO delays do not include "overlap" under 35 U.S.C. § 154(b)(2)(A). Applicant delay is deducted from the PTO delay to arrive at the PTA.

### **PTO Practice Prior to *Wyeth***

Prior to the Federal Circuit's holding in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), the PTO interpreted "no overlap" under 35 U.S.C. § 154 to mean that any A

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delay would necessarily result in B delay. Thus, an applicant was entitled to a PTA equal to the greater of the two types of delay, but not both.

**The Correct Calculation under *Wyeth***

In *Wyeth*, the Federal Circuit stated that: “[n]o overlap happens unless the violations occur at the same time.” *Id.* at 1369-70. According to *Wyeth*, an applicant can be entitled to both A and B delays because no B delay occurs before the 3-year pendancy date. Thus, there can be no overlap for A delays occurring before the 3-year pendancy date.

**The PTO’s Old Calculation Deprived the Applicant of 336 Days of PTA**

The PTO calculated 668 days of PTA for the instant ‘100 patent. As illustrated below, the correct calculation under *Wyeth* is 1004 days. A copy of the prosecution history, downloaded from the PTO’s PAIR database is attached as Exhibit A.

(a) A Delays

(i) 37 CFR 1.702(a)(2). Applicant filed a Response after Non-Final Action on January 14, 2005. The PTO mailed an *Ex Parte Quayle* Action on May 31, 2005. The PTO Action was 17 days beyond 4-months from the May 31, 2005 Response, resulting in a 17 day A delay.

(ii) 37 CFR 1.702(a)(2). Applicant filed a Response after *Ex Parte Quayle* Action on June 27, 2005. The PTO’s next Office Action was mailed on October

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4, 2007. This Action was 707 days beyond 4 months from the June 27, 2005 Response, resulting in a 707 day A delay.

(b) B Delay

37 CFR 1.702(b). The '349 application was filed on September 11, 2003. A Request for Continued Examination (RCE) was filed on September 15, 2008. This resulted in a B delay of 735 days as follows. Three years from September 11, 2003 is September 11, 2006. The interval between September 11, 2006 and the September 15, 2008 RCE filing date is 735 days.

(c) Overlap

37 CFR 1.703(f). The overlap is the period of A delay extending beyond the 3-year pendency date into the B delay period. Here, this is the period from September 6, 2006 to October 4, 2007 and is an overlap of 388 days.

(d) Non-overlapped PTO Delay

The non-overlap delay is  $17 + 707 + 735 - 338 = 1,071$  days.

(e) Applicant Delays under 37 CFR 1.704

(i) Applicant delay was 61 days for the period in excess of three months for the Response filed March 5, 2008 following the October 4, 2007 Non-Final Rejection;

(ii) Applicant delayed 3 days for the period in excess of three months from the RCE filed September 15, 2008 following the June 12, 2008 Final Rejection, and

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(iii) Applicant delayed 3 days for the period in excess of three months for the Issue Fee payment received February 20, 2009 following the November 17, 2008 Notice of Allowance.

(iv) The total applicant delay was  $61 + 3 + 3 = 67$  days.

**PTA under *Wyeth***

The correct PTA is  $1,071 - 67 = 1,004$  days.

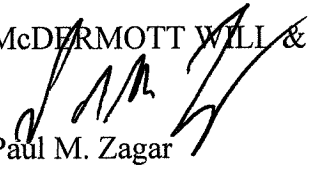
**Conclusion**

As detailed above, the '100 patent should have been granted 1,004 days of PTA. The PTO, using the old, incorrect calculation method, granted 668 days of PTA. Thus, the applicant was deprived of 336 days of patent term adjustment it should have been accorded under the statute. Applicant respectfully requests reconsideration and recalculation of the PTA.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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# EXHIBIT A

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10/660,349

## CONTROLLED RELEASE HYDROCODONE FORMULATIONS

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## Transaction History

Date	Transaction Description
04-07-2009	Recordation of Patent Grant Mailed
03-18-2009	Issue Notification Mailed
04-07-2009	Patent Issue Date Used in PTA Calculation
02-26-2009	Dispatch to FDC
02-25-2009	Application Is Considered Ready for Issue
02-20-2009	Issue Fee Payment Verified
02-20-2009	Issue Fee Payment Received
11-17-2008	Mail Examiner's Amendment
11-17-2008	Mail Notice of Allowance
11-14-2008	Document Verification
11-14-2008	Notice of Allowance Data Verification Completed
11-10-2008	Examiner's Amendment Communication
09-22-2008	Information Disclosure Statement considered
09-22-2008	Reference capture on IDS
09-22-2008	Information Disclosure Statement (IDS) Filed
10-22-2008	Date Forwarded to Examiner
10-22-2008	Date Forwarded to Examiner
09-15-2008	Request for Continued Examination (RCE)
10-22-2008	Disposal for a RCE / CPA / R129
10-04-2008	Case Docketed to Examiner in GAU
09-22-2008	Information Disclosure Statement (IDS) Filed
09-15-2008	Workflow - Request for RCE - Begin
06-12-2008	Mail Final Rejection (PTOL - 326)
06-09-2008	Final Rejection
11-13-2007	Information Disclosure Statement considered
04-05-2008	Date Forwarded to Examiner
03-05-2008	Response after Non-Final Action
03-05-2008	Request for Extension of Time - Granted
01-08-2008	Case Docketed to Examiner in GAU
11-13-2007	Reference capture on IDS
11-13-2007	Information Disclosure Statement (IDS) Filed
11-13-2007	Information Disclosure Statement (IDS) Filed
10-04-2007	Mail Non-Final Rejection
10-01-2007	Non-Final Rejection
01-14-2005	Information Disclosure Statement considered
09-11-2003	Information Disclosure Statement considered
04-19-2007	Case Docketed to Examiner in GAU
06-27-2005	Oath or Declaration Filed (Including Supplemental)
04-17-2007	Date Forwarded to Examiner
06-27-2005	Response after Ex Parte Quayle Action
05-02-2006	Case Docketed to Examiner in GAU
08-28-2005	Case Docketed to Examiner in GAU
05-31-2005	Mail Ex Parte Quayle Action (PTOL - 326)
05-26-2005	Ex Parte Quayle Action
05-18-2005	Case Docketed to Examiner in GAU
05-17-2005	Paralegal TD Not accepted
09-11-2003	Preliminary Amendment
04-05-2005	Case Docketed to Examiner in GAU
01-14-2005	Information Disclosure Statement (IDS) Filed
01-14-2005	Information Disclosure Statement (IDS) Filed

02-11-2005	Date Forwarded to Examiner
01-14-2005	Response after Non-Final Action
01-14-2005	Workflow incoming amendment IFW
10-15-2004	Mail Non-Final Rejection
10-01-2004	Non-Final Rejection
07-08-2004	Case Docketed to Examiner in GAU
07-08-2004	IFW TSS Processing by Tech Center Complete
09-11-2003	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received
09-11-2003	Reference capture on IDS
09-11-2003	Information Disclosure Statement (IDS) Filed
09-11-2003	Information Disclosure Statement (IDS) Filed
12-05-2003	Application Is Now Complete
12-04-2003	Application Return from OIPE
12-05-2003	Application Is Now Complete
12-04-2003	Application Return TO OIPE
12-04-2003	Application Dispatched from OIPE
12-04-2003	Application Is Now Complete
11-24-2003	Cleared by OIPE CSR
10-20-2003	IFW Scan & PACR Auto Security Review
09-11-2003	Initial Exam Team nn

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